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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/868,894

07/05/2001

Kiyoshi Taniguchi

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12/08/2004

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ALEXANDRIA, VA 22314

EXAMINER

ANDERSON, REBECCA L

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,894

Applicant(s)

TANIGUCHI ET AL.

Examiner

Rebecca L Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-29, 31, 36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) 22, 28, 29, 31, 36 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-21 and 23-27 is/are rejected.
- 7) ☒ Claim(s) 18-21 and 23-27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/02, 10/02, 1/10/5761
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

Claims 18-29, 31, 36 and 37 are currently pending in the instant application.

Claims 1821 and 23-27 are rejected and objected to as containing non-elected subject matter and claims 22, 28, 29, 31, 36 and 37 are withdrawn from consideration as being for non-elected inventions.

Election/Restrictions

Applicant's election with traverse of the Group, claims 18-27, drawn to products of the formula (I) , wherein:

R¹ (or R1) is phenyl, optionally substituted by (C1)-(C31), as defined in claim 23

R² (or R2) is carboxy or hydroxyaminocarbonyl

Ar is thienyl

A is trimethylene

X is a single bond

Y is thia, sulfinyl or sulfonyl

Z is methylene

m and n are each an integer of 0 to 6, and 1 is less than or equal to (m+n) which is less than or equal to 6, and salts thereof.

in the reply filed on 20 September 2004 is acknowledged. Claim 22 is therefore withdrawn from consideration as being for a non-elected invention since it is not drawn to the elected invention identified supra along with claims 28, 29, 31, 36 and 37. The traversal is on the ground(s) that the examiner has not provided a proper determination as to why the claims lack unity with each other, in terms of a specific description of the unique technical feature in each exemplary group, that the alternatives defined in a single claim shall meet the technical relationship requirements of PCT Rule 132. if they are of a similar nature, that the office has not applied the same standard of unity of invention as the International Authority, that the office has not shown that a burden

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exists and that the restriction appears to be an election of species. This is not found persuasive because as stated in the previous office action, the claims herein lack unity of invention under PCT rule 13.1 and 13.2 since, under 37 CFR 1.475(a) the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The technical feature of the instant claims is a CH₂ group, which does not define a contribution over the prior art (as can be seen by the references on the submitted 1449). The variables on the group CH₂ group vary extensively and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. As stated in 37 CFR 1.475, the unity of Invention may be determined by the International Searching Authority, the International Examination Authority or during the national stage, i.e., at any time during prosecution. Additionally, although burdensome search is not a requirement when evaluating a lack of unity of invention, the inventions are independent and distinct because there is no patentable co-action between the groups and a reference anticipating one member will not render another obvious. Each group is directed to art recognized divergent subject matter which require different searching strategies for each group. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner. Additionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter imposes a serious burden on any examination of the claimed

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subject matter. Finally, as stated in the previous office action, this is a lack of unity requirement based on the claims lacking a significant structural element qualifying as the special technical feature that defines a contribution over the prior art and not an election of species requirement. Upon the time of finding the product claims allowable, the withdrawn process and method claims of the same scope of the allowable product claims will be rejoined. Therefore, the requirement is still deemed proper.

Claim Objections

Claims 18-27 are objected to as containing non-elected subject matter. Claims 18-27 presented drawn solely to the elected invention identified supra and on page 6 of applicants' response filed 20 September 2004 and free of the following double patenting rejection would appear allowable over the prior art of record.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-21 and 23-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 25 of copending Application No. 10/487242. Although the conflicting claims are not identical, they are not patentably distinct from each other because Applicants elected invention is the products of the formula (I) wherein:

R¹ (or R1) is phenyl, optionally substituted by (C1)-(C31), as defined in claim 23

R² (or R2) is carboxy or hydroxyaminocarbonyl

Ar is thienyl

A is trimethylene

X is a single bond

Y is thia, sulfinyl or sulfonyl

Z is methylene

m and n are each an integer of 0 to 6, and 1 is less than or equal to (m+n) which is less than or equal to 6, and salts thereof.

Conflicting claims 1-10 and 25 claim products of the formula (I) which overlap with applicants instantly claimed elected invention and correspond to applicants elected invention wherein Ar is thienyl, X is a single bond, Y is sulfonyl, Z is methylene, m is 0 and n is 1. Furthermore, conflicting claim 1 includes optionally substituted phenyl for R1 and carboxy as R2. Conflicting claim 3 provides preferences towards R2 as carboxy and conflicting claims 2-10 provide preferences towards R1 as optionally substituted phenyl, specifically, for example, substituted with lower alkyl, amino, hydroxy (conflicting

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claim 2), R1 as optionally substituted phenyl, specifically substituted with, for example, lower alkyl, amino, hydroxy and R2 as carboxy (conflicting claims 3-5, 9 and 10), 4-(n-propyl)phenyl, 4-hydroxyphenyl, etc. for R1 and carboxy for R2 (conflicting claim 6), and phenylphenyl for R1 and R2 as carboxy (conflicting claims 7 and 8)

Therefore, one of ordinary skill in the art when faced with conflicting claims 1-10 and 25 of US Patent Application 10/487,242 would be motivated to prepare more products of the conflicting formula (I) for the treatment of diseases, wherein R1 is substituted phenyl and R2 is carboxy since claims 3-10 provide preferences and motivation to prepare the product of the conflicting formula (I) wherein R1 as phenyl substituted with lower alkyl, amino, hydroxy and phenyl and R2 as carboxy, of which applicants instant elected invention is obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RA

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12/6/04

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